THE WEINBERG GROUP INC.

1220 Nineteenth St, NW, Suite 300
Washington, DC 20036-2400
Phone 202.833.8077
Fax 202.833.7057
e-mail science@weinberggroup.com

WASHINGTON
NEW YORK
SAN FRANCISCO
BRUSSELS
PARIS

March 23, 2004

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
HFA-305, Room 1061
5630 Fishers Lane
Rockville, MD 20852

SUITABILITY PETITION

This petition is submitted pursuant to 21 CFR §10.20 and §10.30, as provided for in 21 CFR §314.93 and Section 505(j)(2)(c) of the Federal Food, Drug and Cosmetic Act, to request the Commissioner of the Food and Drug Administration (FDA) to declare that the drug product Oxycodone Hydrochloride Tablets for oral administration in 5 mg, 10 mg and 20 mg strengths are suitable for submission as an abbreviated new drug application (ANDA).

A. Action Requested

The petitioner requests that the Commissioner of the Food and Drug Administration declare that Oxycodone Hydrochloride 5 mg, 10 mg and 20 mg tablets are suitable for submission as an ANDA. The reference listed drug product upon which this petition is based is Roxicodone™ (oxycodone hydrochloride tablets USP), approved in 15 mg and 30 mg dosage strengths, under New Drug Application (NDA) 21-011. This petition is submitted for a change in dosage strength from the reference drug product. Oxycodone Hydrochloride Tablets will be marketed as immediate-release tablets in dosage strengths of 5 mg, 10 mg and 20 mg. The drug, the route of administration, and the recommendations for use are the same as those of the listed drug product. The proposed product would differ only in dosage strength from the Roxicodone™ marketed product.

The proposed drug product is expected to demonstrate bioequivalence to the 15 mg tablet dosage form of the listed product; data will be submitted at a later date.

B. Statement of Grounds

The Federal Food, Drug, and Cosmetic Act provides for the submission of an ANDA for a new drug that differs in dosage strength from that of a listed drug provided the FDA has approved a petition that proposed the filing of such an application. This petition requests a change in strength for the proposed drug from that of the reference listed drug.

2004P-0148

CP 1

According to the approved labeling for the reference listed drug product, Roxicodone™ (oxycodone hydrochloride tablets, 15 mg and 30 mg), the starting dosage for the management of moderate to severe pain in opioid naïve patients is "5 mg to 15 mg every 4 to 6 hours as needed for pain", and "the dose should be titrated based on the individual patient's response to their initial dose of Roxicodone™", and "a gradual increase in dosage may be required". For patients with chronic pain, Roxicodone™ should be administered on a regular schedule every 4 to 6 hours, at the lowest dose that will achieve analgesia. The dosage strength should be individually adjusted according to severity of pain, response to pain, and patient size. The proposed package insert for the Oxycodone Hydrochloride 5 mg, 10 mg and 20 mg tablets, will be consistent with the reference listed drug labeling. Also, the approved labeling for Roxicodone™ is for both the 15 mg dose and a 30 mg dosage strength. The labeling for the proposed strength of 20 mg will therefore be within the range of therapy allowed for in the approved label.

In summary, the proposed change in strength of Oxycodone Hydrochloride Tablets from that of the reference listed drug (i.e. a change from 15 mg and 30 mg to 5 mg, 10 mg and 20 mg) will not raise questions of safety or efficacy of the proposed product. The reference product labeling recommends titrating the dose of Oxycodone Hydrochloride Tablets so that the strength of analgesia can be adjusted on an individual patient basis. The proposed dosage strengths of 5 mg, 10 mg, and 20 mg will offer intermediate dosage strengths and allow physician's greater flexibility in dosing patients based on their individual need for analgesia. The efficacy of the proposed 5 mg and 10 mg dosage strengths is supported in the reference product labeling, where it recommends a dose of 5 to 15 mg every 4 to 6 hours. The proposed 20 mg tablet dosage strength would allow for a dosage strength between the currently approved 15 mg and 30 mg doses when, as the reference labeling states, "if the pain increases in severity, if analgesia is not adequate, or if tolerance occurs, a gradual increase in dosage may be required". The approval of a 20 mg strength would therefore not present additional safety concerns because it is within the range of currently approved therapy.

The proposed product will differ from the listed drug only in dosage strength. The indications, route of administration, intended patient population, and recommendations for use will remain the same as for the Roxicodone™ product. Therefore, there will be no difference in the safety and efficacy of the proposed strengths of Oxycodone Hydrochloride Tablets.

The package insert for Roxicodone™ is provided in Attachment 1 of this petition. The draft package insert for the proposed Oxycodone Hydrochloride 5mg, 10 mg and 20 mg tablets is provided in Attachment 2.

C. Pediatric Use Information

The Pediatric Research Equity Act, passed in December 2003, requires that applications submitted under section 505 of the Act, be evaluated for safety and efficacy in pediatric populations when the application is submitted for the following: A new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration. The proposed petition seeks a change in dosage strength from that of the reference listed

product, and therefore under the provisions of the Pediatric Research Equity Act, it is not necessary to evaluate the safety or efficacy in pediatric populations or seek a waiver or deferral for pediatric studies. Further support that this petition for a change in dosage strength is not subject to the Pediatric Research Equity Act was further clarified in a letter received from FDA (see Attachment 3). A letter from the Office of Generic Drugs received on December 18, 2003 in correspondence to a suitability petition submitted for a change in strength stated that, "under the Pediatric Research Equity Act, which was signed December 2003, it is not necessary to seek a waiver or deferral of pediatric studies for a change in strength". The package insert of the listed drug, Roxicodone™, states that "The safety and efficacy of oxycodone IR in pediatric patients has not been evaluated". The proposed package insert for Oxycodone Hydrochloride 5 mg, 10 mg and 20 mg tablets will provide the same information for pediatric use as the reference product, Roxicodone™, and because the proposed change is a change in strength, no additional studies should be required.

D. Environmental Impact

An environmental assessment report on the action requested in this petition is not required under 21 CFR §25.31.

E. Economic Impact

The petitioner does not believe that this is applicable in this case, but will agree to provide such an analysis if requested by the agency.

F. Certification

The undersigned certifies that to the best of his knowledge, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Sincerely,

Nicholas M. Fleischer, R.Ph., Ph.D.
Director of Biopharmaceutics
THE WEINBERG GROUP INC.

NMF/kh

Enclosures

cc Gary Buehler, Director, Office of Generic Drugs (w/encls.)